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Mail Stop Amendment

Art Unit 1653

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 09/529,130; § 371 Date: June 22, 2000

Conjugates of Galactose-Binding Lectins and Clostridial Neurotoxins

as Analgesics

Inventors:

Duggan et al.

Our Ref:

1581.0580000/RWE/ALS

Sir:

Transmitted herewith for appropriate action are the following documents:

- Credit Card Payment Form PTO-2038; 1.
- Sixth Supplemental Information Disclosure Statement; 2.
- 3. Four (4) pages of Form PTO-1449 citing sixteen (16) documents;
- Copies of six (6) cited documents; and 4.
- 5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE KESSLER GOLDSTEIN & FOX P.L.L.C.

Aaron L. Schwartz Attorney for Applicants Registration No. 48,181

RWE/ALS/law Enclosures 377134v1

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In re application of:

Confirmation No.: 2901

Duggan et al.

Art Unit:

1653

Appl. No.: 09/529,130

Examiner:

Kam, Chih Min

§ 371 Date: June 22, 2000

Atty. Docket: 1581.0580000/RWE/ALS

For: Conjugates of Galactose-Binding

Lectins and Clostridial **Neurotoxins as Analgesics**

Sixth Supplemental Information Disclosure Statement Under 37 C.F.R. § 1.97(c)

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450 Mail Stop: Amendment Art Unit 1653

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Sixth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Fifth Supplemental Information Disclosure Statement filed on December 9, 2004 in connection with the above-captioned application.

Copies of documents AS17 to AR19 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, documents AE1 to AK1, cited on the attached Form PTO-1449 are not submitted. In addition, copies of documents AS19 to AR20 are not provided in accordance with the U.S. Patent and Trademark Office OG notice of October 19, 2004, which states: "the requirement in 37 C.F.R. § 1.98(a)(2)(iii) for a legible copy of the specification, including the claims, and drawings of each cited pending U.S. patent application (or portion of the application which caused it to be listed) is sua sponte waived where the cited pending application is stored in the USPTO's IFW system."

The Examiner's attention is directed to documents AE1-AK1, which are directed to related technical subject matter. The Examiner's attention is also directed to documents AS17-AR20, which are applications or prosecution histories of previously filed or co-pending patent applications which are directed to related technical subject matter. The identification of these U.S. Patent Applications and their respective prosecution histories are not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent

Duggan et al. Appl. No. 09/529,130

application does not exist. The Examiner is specifically requested not to rely solely on

- 3 -

the material submitted herewith.

This Information Disclosure Statement is being filed more than three months

after the U.S. filing date and after the mailing date of the first Office Action on the

merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an

action that otherwise closes prosecution in the application. Attached is our PTO-2038

Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37

C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the

enclosed Form PTO-1449, and indicate in the official file wrapper of this patent

application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee

deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Aaron L. Schwartz

Attorney for Applicants

Registration No. 48,181

Date:

March 31, 2005

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

376453_1.DOC

Page 1 of 4 APPLICATION NO. ATTY. DOCKET NO. 09/529,130 1581.0580000/RWE/ALS FIRST NAMED INVENTOR FORM PTO-144 Michael John Duggan SIXTH SUPPLEMENTAL INFORMATION INC. ART UNIT § 371 DATE 1653 June 22, 2000 **U.S. PATENT DOCUMENTS** SUB-CLASS FILING DATE DOCUMENT **EXAMINER** CLASS NAME DATE NUMBER INITIAL AA AB AC AD 05/28/2002 Foster et al. 6,395,513 B1 AE1 Shone et al. 10/08/2002 6,461,617 B1 AF1 Quinn et al. 10/14/2003 6,632,440 B1 AG1 Shone et al. 08/07/2003 2003/0147895 A1 AH1 Shone et al. 09/04/2003 2003/0166238 A1 Al1 Quinn et al. 2004/0071736 A1 04/15/2004 AJ1 Foster et al. 03/13/2003 2003/0049264 A1 AK1 FOREIGN PATENT DOCUMENTS TRANSLATION DOCUMENT SUB-CLASS **EXAMINER** CLASS COUNTRY DATE NUMBER Yes INITIAL No Yes AL No AM Yes No Yes ΑN No AO Yes No ΑP OTHER (Including Author, Title, Date, Pertinent Pages, etc.) AR Copy of application and Prosecution History for "Recombinant Toxin Fragments," Shone et al., U.S. Application No. 09/255,829, filed February 23, 1999 <u>17</u> AS Copy of Application and Prosecution History for "Methods and Compounds for the Treatment of Mucus Hypersecretion," Quinn et al., U.S. Application No. 09/763,669, with a §371 date

EXAMINER EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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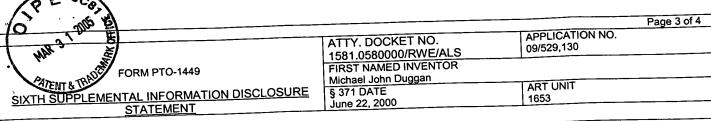
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Page 4 of 4

ATTY. DOCKET NO. 1581.0580000/RWE/ALS 09/529,130

FIRST NAMED INVENTOR Michael John Duggan

§ 371 DATE June 22, 2000 1653

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Quinn et al.

Appl. No. To be assigned

Filed: Herewith

For: Methods and Compounds for the

Treatment of Mucus Hypersecretion

Art Unit: To be assigned

Examiner: To be assigned

Atty. Docket: 1581.0770001/RWE/BEC

Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/763,669, filed May 29, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not

Quinn et al. Appl. No. To be assigned

-2-

be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Ba E. Clale

Bruce E. Chalker Attorney for Applicants Registration No. 47,480

Date: August 5, 2003

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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APPLICATION NO. ATTY. DOCKET NO. 1581.0770001/RWE/BEC To be assigned FORM PTO-1449 APPLICANT To be assigned INFORMATION DISCLOSURE STATEMENT FILING DATE GROUP To be assigned Herewith U.S. PATENT DOCUMENTS EXAMINER FILING DATE CLASS SUB-CLASS NAME DOCUMENT NUMBER DATE INITIAL AA ΑВ AC AD ΑE ΑF AG AΗ ΑĪ AJ AK FOREIGN PATENT DOCUMENTS EXAMINER SUB-CLASS TRANSLATION CLASS COUNTRY DATE DOCUMENT NUMBER INITIAL Yes No WIPO 04/17/1997 WO 97/13410 AL2 Yes No 02/26/1998 WIPO WO 98/07684 AM2 Yes No 02/26/1998 WIPO WO 98/07864 AN2 Yes No ΑO Yes No AP OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Nishiki, T., et al., "Identification of Protein Receptor for Clostridium botulinum Type B Neurotoxin in Rat Brain Synaptosomes, " J. Biol. Chem. 269:10498-10503, American Society for Biochemistry and Molecular Biology, Inc. AR <u>2</u> (1994) Nishiki, T., et al., "The high-affinity binding of Clostridium botulinum type B neurotoxin to synaptotagmin II associated with gangliosides $G_{\text{Tib}}/G_{\text{Dia}}$," FEBS AS 2 Lett. 378:253-257, Federation of European Biochemical Societies (1996) Poulain, B., et al., "Inhibition of transmitter release by botulinum neurotoxin A. Contributions of various fragments to the intoxication process, " Eur. J. AΤ <u>2</u> Biochem. 185:197-203, Federation of European Biochemical Societies (1989) DATE CONSIDERED EXAMINER **EXAMINER**: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Quinn et al.

Appl. No. To be assigned

Filed: Herewith

For: Methods and Compounds for the

Treatment of Mucus Hypersecretion

Confirmation No.

Art Unit: To be assigned

Examiner: To be assigned

Atty. Docket: 1581.0770001/RWE/BEC

First Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

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Quinn et al. Appl. No. To be assigned

- 2 -

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Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

B- E. Clark

Bruce E. Chalker Attorney for Applicants Registration No. 47,480

Date: August 5, 2003

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

DATE CONSIDERED

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Page 2 of 3

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communication to Applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Quinn et al.

Appl. No. To be assigned

Filed: Herewith

For: Methods and Compounds for the

Treatment of Mucus Hypersecretion

Art Unit: To be assigned

Examiner: To be assigned

Atty. Docket: 1581.0770001/RWE/BEC

Second Supplemental Information Disclosure Statement

Commissioner for Patents Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Second Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' First Supplemental Information Disclosure Statement filed herewith, in connection with the above-captioned application. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/763,669, filed May 29, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Document AP2, German Patent No. DE 197 35 105 A1, is in the German language. The relevance of Document AP2 can be ascertained by reference to Document AR6, which is an English-language abstract of this German patent.

Document AM4, WO 99/58571, is in the German language. The relevance of document AM4 can be ascertained by reference to Document AS6, which is an Englishlanguage abstract of this published international patent application.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on

information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

This Second Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Bon E. Chulher

Bruce E. Chalker Attorney for Applicants Registration No. 47,480

Date: August 5, 2003

1100 New York Avenue, N.W. Suite 600 Washington, D.C. 20005-3934 (202) 371-2600

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Quinn et al.

Appl. No. To be assigned

Filed: Herewith

For: Methods and Compounds for the

Treatment of Mucus Hypersecretion

Confirmation No.

Art Unit: To be assigned

Examiner: To be assigned

Atty. Docket: 1581.0770001/RWE/BEC

Third Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Third Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Second Supplemental Information Disclosure Statement filed herewith in connection with the above-captioned application. A copy of each document is also provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Quinn et al. Appl. No. To be assigned

- 2 -

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

This Third Supplemental Information Disclosure Statement is being filed within three months of the filing date OR before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

B- E. Chille

Bruce E. Chalker Attorney for Applicants Registration No. 47,480

Date: August 5, 2003

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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